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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/30/2003

Jason A. Demers

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07/16/2010

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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

07/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,969	Applicant(s) DEMERS ET AL.	
	Examiner MARCELA M. CORDERO GARCIA	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,27,29-42,44-50 and 52-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,27,29-42,44-50 and 52-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 filed on 9/14/09 was previously entered.

2. This Office Action is in response to the reply filed on 4/9/2010. Applicant's arguments, filed 4/29/2010, with respect to the rejection(s) of record have been fully considered and are persuasive based on applicant's amendments.

Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is necessary in view of applicant's amendments to the claims (see 112 1st rejection below).

Status of the claims

3. Claims 26-71 were previously pending. Claims 43 and 66 were previously cancelled. Claims 26, 27, 28, 29, 30, 31, 33, 34, 36, 37, 40, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 56, 57, 59, 60, 61, 67, 68, 69, 70 and 71 were amended. Claims 26-42, 44-65, 67-71 were previously pending. Claims 28, 43, 51 and 66 have now been canceled. Claims 26, 30, 37, 48, 49, 53 and 60 have been now amended. Claims 26-27, 29-42, 44-50, 52-65 are currently pending and are presented for examination on the merits.

Claim rejections -112 1st paragraph

4. Claims 26-27, 29-42, 44-50, 52-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter

5. The claims have been amended (cf. amendment filed 4/9/2010) as follows: Claim 26 has been amended to recite that the container spiking assembly controller controls the movement of at least a portion of the container spiking assembly to couple the container receptacle with the port assembly. Claim 49 has been amended to recite that the coupling means controls the movement of at least a portion of the positioning means to couple the container receptacle with the port assembly. Applicants indicate that support for the amendments filed on 4/9/2010 can be found at least, for example in paragraphs 0128-0141 and Figures 9A-9E of the application as filed.

Lack of Ipsis Verbis Support

6. Applicants indicate that support for the amendments filed on 4/9/2010 can be found at least, for example in paragraphs 0128-0141 and Figures 9A-9E of the application as filed. However, applicants did not expressly indicate what portions of these paragraphs and figures support. However, review of these paragraphs void does not clearly show support for the instant amendments. One of the amendments (claim 26) is the change of “the coupling surfaces of the container receptacle and port assembly are adapted and configured to resist decoupling” for –the container spiking assembly controller controls the movement of at least a portion of the container spiking assembly to couple the container receptacle with the port assembly--. The other change (claim 49) involves

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changing “means for securing” for – means for positioning—and “the coupling surfaces of the container receptacle and port assembly are adapted and configured to resist decoupling” for –the coupling means includes means for causing movement of at least a portion of the positioning means to couple the container receptacle with the port assembly.--. However, review of the instantly claimed amendments indicates that such changes do not necessarily appear to be supported by the disclosure. For instance, paragraph 0129, referring to Figure 9E, does indicate that once the vial assembly 200 and spike receptacle 310 are positioned and locked in place, the bladder 918 can be inflated to cause the bladder plate 906 to push the shaft 920 and piston 904 upward. However, the claims as now amended do not require securing (i.e., locking in place) but only positioning. Also, it is not clear where the support for “controls the movement of *at least a portion* of the container spiking assembly” is to be found. For example, in In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), the Court rejected a claim species that fell within a large genus. The Court analogized the genus of the compounds to a forest and the species to a tree. The Court stated “[i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail... to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.” Ruschig, 154 USPQ at 122. Similarly, in Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895, the Federal Circuit declined to find support for a subgenus based on the disclosure of a genus because the application did not contain “blazemarks” to support the

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subgenus. In justification for denying support, the Court stated that “just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety.”

Fujikawa, 39 USPQ2d at 1905. Thus it is clear from these decisions that the specification must provide blazemarks to the new sub-genus or species.

Lack of Inherent Support

7. “While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” MPEP 2105 states that “A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonable lead” those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). In the instant case, as set forth above, the disclosure at paragraph 0129, referring to Figure 9E, does indicate that once the vial assembly 200 and spike receptacle 310 are positioned and locked in place, the bladder 918 can be inflated to cause the bladder plate 906 to push the shaft 920 and piston 904 upward. However, the claims as now amended are drawn to a container spiking assembly for positioning the container receptacle next to the port assembly and do not require securing (i.e., locking in place). Also, it is not clear where the support for “controls

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the movement of *at least a portion* of the container spiking assembly” is to be found. Therefore, the instantly carved and claimed subgenus does not appear to be adequately supported by the instant disclosure.

Conclusion

8. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose

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telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

MMCG 07/2010